

## REMARKS

In the Office Action mailed on July 24, 2006, the Examiner has made a request to Applicant to file a proper priority claim in compliance with the requirements of 37 CFR 1.63(c). Accordingly, Applicant has provided a supplemental ADS with the foreign priority properly identified by its application number and filing.

In Section 3 of the Office Action, the Examiner has objected the disclosure due to the informalities. Applicant has amended the corresponding paragraphs and tables in the specification accordingly.

In Section 4 of the Office Action, the Examiner has rejected Claims 15 and 16 under 35 U.S.C. § 101 because the claimed invention is directed to non-statutory subject matter. Applicant has amended Claims 15 and 16 to direct towards to a method of using the polypeptides for the treatment of rheumatoid arthritis, thus rendering the rejections moot. The supporting languages can be found through the disclosure, especially in Example 3 (page 7, line 24 to page 10, line 8).

In Section 5 of the Office Action, the Examiner has further rejected Claims 15 and 16 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In light of the amendment of these two claims, the rejections are also rendered moot.

In Section 6 of the Office Action, the Examiner has objected Claims 11-16 due to informalities. Applicant has amended accordingly in compliance with the requests of the Examiner.

In Section 8 of the Office Action, the Examiner has rejected Claims 11-16 under 35 U.S.C. § 102(b) as being anticipated by Andersson (PNAS, Vol. 95, pages 7574-7579). The rejections are respectfully traversed. Andersson teaches peptides each having 13 amino acids (see page 7575, Table 1), whereas the peptides in Applicant's invention each comprises 10 amino acids and lack the amino acids corresponding to positions 261, 262 and 273 in CII protein. To better reflect the invention disclosed in the original application, Applicant has now amended Claim 11 by specifying that the peptide is a ten-amino acid peptide. The supporting language can be found on page 3, lines 32-36 and page 6, Table 2. Thus, Applicant's invention is patentably distinguished from Andersson.

Reconsideration of the rejection is respectfully requested. Since Claims 12-16 are dependent from the independent claim 1, reconsideration of the rejections against them is also respectfully requested in light of the newly amended claim 1.

Applicant also submits that it is well documented that the biological activity of a peptide originated from CII protein is extremely sensitive to its sequence length. As demonstrated by Fugger et al. (Eur. J. Immunol. (1996), Vol. 26, pages 928-933), the IC<sub>50</sub> of a 13-amino acid peptide corresponding to the amino acid sequence 264-273 of CII protein is 140 nM. However, the IC<sub>50</sub> of a 10-amino acid peptide corresponding to the sequence 264-273 of CII protein is greater than 100,000 nM. By a simple deletion of three amino acids at one end, the activity of the peptide corresponding essentially to the same region of CII protein, the biological activity is dramatically decreased, a 700-fold increase in the IC<sub>50</sub> value. Furthermore, Andersson has also taught that the three amino acid residues, which are absent from Applicant's invention, play important roles in their binding interactions. As illustrated in Table 1 (page 7575), the IC<sub>50</sub> of the natural CII 261-273 sequence was 180 nM, Ala substitution of Gly-262 resulted in a 3-fold decrease in IC<sub>50</sub> (52 nM) and Gly-262 was further identified as a T cell contact point for hybridoma E11 (see page 7576, right column, line 3-5 of D1). In considering the importance of Gly262, it would be reasonably believed that a skilled artisan will not have the motivation to delete Gly262 together with Ala161.

Appl. No. 10/519,524  
Amdt. dated October 20, 2006  
Reply to Office Action of July 24, 2006

**STATEMENT UNDER 37 C.F.R. § 1.821(f) AND (g)**

The original sequence listing is amended herein and a computer readable sequence listing, as required by C.F.R. § 1825(b), and a paper copy of the amended sequence list as substitute sheets, as required by C.F.R. § 1.825(a), are submitted herewith. Two compact disks were generated using PatentIn 3.3 on Windows XP. The undersigned agent states that, as required under 37 C.F.R. § 1.825(a), the sequences on the substitute sheets do not include new matter and the information recorded in computer readable form is identical to the written sequence listing on the substitute sheets.

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## SUMMARY

It is believed that the foregoing amendment and argument deals with all grounds of objection and rejection, and that the claims remaining in this application are in order for allowance.

Should the Examiner believe that prosecution of this application might be expedited by further discussion of any remaining issue, the Examiner is cordially invited to contact the undersigned representative for the Applicant by phone at (619) 230-7457 or by email at [lyu@gordonrees.com](mailto:lyu@gordonrees.com).

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 50-1990 and please credit any excess fees to such deposit account.

Respectfully submitted,

Dated: October 20, 2006

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